

# **Exhibit 7**

**From:** Carr, Jessica [Jessica.Carr@fda.hhs.gov]  
**Sent:** 9/23/2021 4:00:23 PM  
**To:** Connor McCarty [Connor.McCarty@intusurg.com]  
**Subject:** RE: [EXTERNAL] K212101 is on Hold Pending Your Response

Hi Connor,

Please see the team's responses to your questions below.

Best regards,  
 Jessica

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**From:** Connor McCarty <Connor.McCarty@intusurg.com>  
**Sent:** Monday, September 20, 2021 10:17 PM  
**To:** Carr, Jessica <Jessica.Carr@fda.hhs.gov>  
**Subject:** RE: [EXTERNAL] K212101 is on Hold Pending Your Response

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Hi Jessica,

We have a couple clarification questions regarding the AINN letter for K212101. Can these be addressed via email in lieu of a teleconference?

1. Regarding Major Deficiencies (i) and (ii), are you requesting reprocessing validation testing for the parent *da Vinci SP* Surgical System surgical instruments? The endoscope (camera) component of the subject device is not considered a surgical instrument, so we believe that the surgical instruments are outside the scope of this submission. Can you confirm that only the endoscope reprocessing testing is being requested?

We are requesting testing for both the endoscope and the surgical instruments. This is because the reprocessing document proposed in this submission contains new use life and reprocessing cycle recommendations for the surgical instruments. You were unable to reference a previous submission in which the use life and reprocessing cycle recommendations for the surgical instruments have been reviewed and found acceptable. Therefore, we are unable to clear the proposed labeling without data supporting the new use life and reprocessing cycle recommendations. We also provided an alternative option of revising the labeling such that the surgical instrument recommendations are consistent with those previously cleared. In that case, expanding the uses and reprocessing cycles could be the subject of a separate submission.

2. On page 2, the letter states: "However, we believe that changes to the reprocessing of your device require a 510(k)." Is this statement referring to the change of (a) adding alternate sterilization containers, (b) increasing the number of uses for the camera, and/or (c) changing the dry time? Specifically, would solely increasing the number of uses for the camera necessarily require a 510(k) submission, if the reprocessing steps for a single cycle are unchanged?

Yes, these changes will require a 510(k) submission even though the reprocessing steps remain unchanged.

This is because your device is listed in Table 1 of Appendix E of FDA's Reprocessing guidance as one that poses greater risks to the public health.

Appendix E and Section VI, Criterion 4, state that complete protocols, test reports, and validation of the cleaning and sterilization instructions should be provided for endoscopic/computer controlled instruments under NAY product code for FDA review, so that FDA has the information it needs to evaluate substantial equivalence and that Reprocessing instructions should be technically feasible and include only devices and accessories that are legally marketed. As such, changes to sterilization containers, number of uses, reprocessing cycles and sterilization parameters would need to be validated and the data be provided for FDA review to demonstrate that the proposed reprocessing instructions will

reprocess the subject device at least as well as the reprocessing instructions for the predicate device. These changes to your devices (camera, endoscope, robotic instruments) require a 510(k) submission.

3. Would you be willing to review responses to the AINN letter informally ahead of a formal response?

I do not have availability to pre-review your proposed responses. However, if not substantive, I am able to provide informal feedback on a proposed approach by email, or more substantive feedback in response to a Submission Issue Request Q-submission.

Thanks,  
Connor

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**From:** Jessica Carr [JESSICA.CARR] <[jessica.carr@fda.hhs.gov](mailto:jessica.carr@fda.hhs.gov)>  
**Sent:** Friday, September 17, 2021 2:19 PM  
**To:** Connor McCarty <[Connor.McCarty@intusurg.com](mailto:Connor.McCarty@intusurg.com)>  
**Cc:** Jessica Carr [JESSICA.CARR] <[jessica.carr@fda.hhs.gov](mailto:jessica.carr@fda.hhs.gov)>  
**Subject:** [EXTERNAL] K212101 is on Hold Pending Your Response

September 17, 2021

We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Jessica Carr.

\*\*\* This is a system-generated email notification \*\*\*

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